anaphylactoid shock. Usual Dosage: Cattle, horses, sheep, and swine—1 cubic centimeter per 100 pounds of body weight. Inject subcutaneously''.

(c) The labeling must also bear a description of the symptoms of anaphylactoid shock including glassy eyes, increased salivation, grinding of the teeth, rapid breathing, muscular tremors, staggering gait, and collapse with death following. These symptoms may appear shortly after injection of a bacterin, vaccine, or antibiotic.

Subpart E—Regulation of Carcinogenic Compounds Used in Food-Producing Animals

SOURCE: 52 FR 49586, Dec. 31, 1987, unless otherwise noted.

§ 500.80 Scope of this subpart.

(a) The Federal Food, Drug, and Cosmetic Act requires that sponsored compounds intended for use in food-producing animals be shown to be safe and that food produced from animals exposed to these compounds be shown to be safe for consumption by people. The statute prohibits the use in food-producing animals of any compound found to induce cancer when ingested by people or animals unless it can be determined by methods of examination prescribed or approved by the Secretary (a function delegated to the Commissioner of Food and Drugs under § 5.10 of this chapter) that no residue of that compound will be found in the food produced from those animals under conditions of use reasonably certain to be followed in practice. This subpart provides an operational definition of no residue and identifies the steps a sponsor of a compound shall follow to secure the approval of the compound. FDA guidance documents contain the procedures and protocols FDA recommends for the implementation of this subpart. These guidance documents are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests for these guidance documents should be identified with Docket No. 83D–0288.

(b) If FDA concludes on the basis of the threshold assessment that a sponsor shall conduct carcinogenicity testing on the sponsored compound, FDA will also determine whether and to what extent the sponsor shall conduct carcinogenicity testing on metabolites of the sponsored compound. The bioassays that a sponsor conducts must be designed to assess carcinogenicity and to determine the quantitative aspects of any carcinogenic response.

(c) If FDA concludes on the basis of the threshold assessment or at a later time during the approval process that the data show that the sponsored compound and its metabolites should not be subject to this subpart, FDA will continue to consider the compound for approval under the general safety provisions of the act for risks other than cancer.

(d) This subpart does not apply to essential nutrients.

[52 FR 49586, Dec. 31, 1987, as amended at 59 FR 14365, Mar. 28, 1994; 62 FR 66983, Dec. 23, 1997; 65 FR 56480, Sept. 19, 2000]

§ 500.82 Definitions.

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this subpart.

(b) The following definitions apply to this subpart:

Act means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 *et seq.* as amended (21 U.S.C. 301–392)).

Essential nutrients means compounds that are found in the tissues of untreated, healthy target animals and not produced in sufficient quantity to support the animal's growth, development, function, or reproduction, e.g., vitamins, *essential* minerals, *essential* amino acids, and *essential* fatty acids. These compounds must be supplied from external sources.

FDA means the Food and Drug Administration.

Marker residue means the residue selected for assay whose concentration is in a known relationship to the concentration of the residue of carcinogenic concern in the last tissue to deplete to its permitted concentration.